DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 10, 2014

Mazor Robotics Ltd.
% Ahava Stein
Regulatory Consultant
A. Stein-Regulatory Affairs Consulting Ltd.
20 Hata'as St. (Beit Hapaamon, Suite 102)
Kfar Saba 44425
Israel

Re: K140167
Trade/Device Name: Renaissance System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO, HAW, LLZ
Dated: August 3, 2014
Received: August 11, 2014

Dear Ahava Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K140167

Device Name: Renaissance System

Indications for Use:

The Renaissance X System is indicated for precise positioning of surgical instruments or implants during general spinal surgery. It may be used in either open or minimally invasive or percutaneous procedures.

Renaissance X 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

Prescription Use __√___ OR Over-The-Counter Use___

(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K140167
(Premarket Notification [510(k)] Number)

1. Submitter Information

Manufacturer Name and Address
Mazor Robotics Ltd.
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Official Correspondent
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Israel

2. Date Prepared: July 28, 2014

3. Device Name Renaissance X System

Proprietary Name: Renaissance X System

Common Name: Combination of:
1. Spinal/Orthopedic Stereotaxic instrument; and
2. System, Image Processing, Radiological

FDA Classification Name: 21 CFR 882.4560; Stereotaxic instrument

FDA Classification: Class II, Product Code OLO, HAW and LLZ

4. Predicate Devices

The Renaissance System is substantially equivalent to the following devices:

Manufacturer	Device	510(k)	Date Cleared
Mazor Robotics Ltd.	Renaissance System	K113228	December 1, 2011

5. Device Description

The Renaissance X System hosts guidance for spine procedures and intra-operative 3D image processing capabilities. It enables the surgeon to precisely position surgical instruments and/or implants. The planning of the surgical procedure and virtual placement of surgical instruments and/or implants (e.g., a screw) can be achieved through pre-operation planning based on the patient's CT scan or intra-operative planning based on Renaissance X 3D Scan image or on a 3D image uploaded from an external 3D image acquiring system. With the imaging capabilities of the system the user can also visualize the implants on the patients CT.

6. Indications for Use

The Renaissance X System is indicated for precise positioning of surgical instruments or implants during general spinal surgery. It may be used in either open or minimally invasive or percutaneous procedures.

Renaissance X 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

7. Performance Standards

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for the Renaissance X System.

8. Performance Testing

The following Performance tests were performed on the Renaissance X System:

- Software validation testing in accordance with the FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software validation tests demonstrate that the modified software version meets its design requirements.
- Accuracy and Repeatability Testing - these tests demonstrate that the Renaissance X System has maintained the required accuracy, as specified in the device design requirement. These tests have established that the system is accurate every time as an integrated system, including the full assembly as will be performed in the Operating Room, and that it is able to repeatedly perform in the same standard when required.
- Rigidity Testing - these tests demonstrate the mechanical integrity of the Renaissance X System. It shows that the system's design meets the functional requirements with safety margins.
- Collision Avoidance Testing - these tests validates the system's ability to avoid collisions in the operating field, both with the patient and various objects used during the operation.

9. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the indications for use of the modified Renaissance X System are substantially equivalent to the predicate device cited above.